FDA

MAUDE Adverse Event Report: EPIC SYSTEMS CORPORATION EPIC EHR EPIC SOFTWARE TRANSMISSION AND STORAGE

EPIC SYSTEMS CORPORATION EPIC EHR EPIC SOFTWARE TRANSMISSION AND STORAGE

Back to Search Results

Event Date 06/10/2017
Event Type Malfunction
Event Description

There was a misidentification of the primary and private physician of this case that resulted in pt info and data being sent to the wrong physician, and a delay in it being distributed to the correct care team. Not only is this a hipaa violation, but it delays care upon transition from hospital. The ehr renders it difficult, if not impossible to, correct the error that populates many fields.

Search Alerts/Recalls[22]

New Search | Submit an Adverse Event Report[23]

Brand Name EPIC EHR
Type of Device EPIC SOFTWARE TRANSMISSION AND STORAGE
Manufacturer *(Section D)* EPIC SYSTEMS CORPORATION
Verona WI 53593
MDR Report Key 6642848
Report Number MW5070405
Device Sequence Number 1
Product Code MMH[24]
Report Source Voluntary
Reporter Occupation Physician
Report Date 06/13/2017
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 06/13/2017
Is This An Adverse Event Report? No
Is This A Product Problem Report? Yes
Device Operator Health Professional
Was Device Available For Evaluation? Yes
Is The Reporter A Health Professional? Yes
Was the Report Sent to FDA?
Event Location No Information
Was Device Evaluated By Manufacturer?
Is The Device Single Use?
Is this a Reprocessed and Reused Single-Use Device? No
Type of Device Usage

Patient TREATMENT DATA
Date Received: 06/13/2017 Patient Sequence Number: 1

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php

3. http://www.fda.gov/default.htm
4. https://www.fda.gov/MedicalDevices/default.htm
5. https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
11. /scripts/cdrh/cfdocs/cfRES/res.cfm
12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm
23. https://www.accessdata.fda.gov/scripts/medwatch/
24. ../cfPCD/classification.cfm?start_search=&ProductCode=MMH

Page Last Updated: 01/31/2019

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Site Map Nondiscrimination Website Policies

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive

U.S. Department of **Health & Human Services**

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain